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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/441,055	11/16/1999	YOSHIHIRO USUDA	0010-1057-0	3806

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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 11/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/441,055		USUDA ET AL.	
	Examiner		Art Unit	
	Christian L. Fronda		1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-33 and 35 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 and 11-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31, 33, 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>09/01/05</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Claims 1-9, 11-33 and 35 are pending in the application. Claims 1-9 and 11-30 are withdrawn from consideration as drawn to a non-elected invention.
2. Claims 31, 33 and 35 are under consideration in this Office Action.
3. The rejection of claims 31, 33 and 35 under 35 U.S.C. 112, second paragraph, as being indefinite has been withdrawn in view of applicants' amendment to the claims filed 09/01/2005.
4. The rejection of claims 31, 33 and 35 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement has been withdrawn in view of applicants amendment to the claims filed 09/01/2005.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

5. Claims 31, 33 and 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' arguments filed 09/01/2005 have been considered but they are not persuasive. Applicants' position is that the specification and the general knowledge in the art fully support the nucleotide sequences for the endogenous *met J*, *metA*, *metK*, *metB*, and *metL* gene of *Escherichia* bacterium. Applicants refer to SEQ ID NOs: 17, 18, 25, and 26; cite the reference of Duchange et al. (reference AX on PTO 1449 dated 09/01/2005) which teaches the *E.coli metJBLF* cluster; and cite the reference of Zakin et al. (reference AX on PTO 1449 dated 09/01/2005) which teaches the *E.coli metL* gene encoding aspartokinase-homoserine dehydrogenase II to support their arguments. The Examiner respectfully disagrees for reasons of record as supplemented below.

As stated in the previous Office Action, according to MPEP §2111, claims must be given their broadest reasonable interpretation consistent with the specification and that such interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach. The claims of the instant invention must be read in light of the specification to

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thereby interpret limitations explicitly recited in the claims. Thus, limitations of the specification, such as SEQ ID NOs: 17, 18, 25, and 26, cannot be read into the claims to narrow the scope of the claims by implicitly adding disclosed limitations which are not recited in the claims.

Furthermore, the nucleotide sequences and structures from the specific species of *E. coli* taught by the references of Duchange et al. and Zakin et al. cannot be read into the claims to narrow the scope of the claims.

Thus, the amended claims encompasses a method using a genus of methionine repressors encoded by a genus of endogenous *metJ* genes of any nucleotide sequence and structure, a genus intracellular homoserine transsuccinylase enzymes encoded by a genus of *metA* genes, a genus S-adenosylmethionine synthetase enzymes encoded by a genus of endogenous *metK* genes, a genus of intracellular cystathionine γ -synthase enzymes encoded by a genus of *metB* genes, and a genus aspartokinase-homoserine dehydrogenase II enzymes encoded by a genus of *metL* genes. The scope of each genus includes many polynucleotides with widely differing nucleotide sequences and structures, where each genus is highly variable because a significant number of structural differences between genus members exists.

In the evaluation of the claims for compliance with the written description requirement of 35 U.S.C. 112, of particular relevance is 66 FR 1099, Friday, January 5, 2001, which states:

Eli Lilly explains that a chemical compound's name does not necessarily convey a written description of the named chemical compound, particularly when a genus of compounds is claimed. *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1405. The name, if it does no more than distinguish the claimed genus from all others by function, does not satisfy the written description requirement because "it does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. Thus *Eli Lilly* identified a set of circumstances in which the words of the claim did not, without more, adequately convey to others that applicants had possession of what they claimed." (see p. 1100, 1st column, line 47 to 2nd column, line 2).

While the specification discloses SEQ ID NOs: 17, 18, 25, and 26; the recitation of the names of each genus (e.g., "*metK*", "*metB*", and "*metL*") and their biological source as *Escherichia* does not define any structural features and nucleotides sequences commonly possessed by each genus. Furthermore, the specification does not describe and define any structural features and nucleotide sequences commonly possessed by each genus. Thus, one

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skilled in the art cannot visualize or recognize the identity of the members of each genus for use in the claimed method.

In view of the above considerations, one of skill in the art would not recognize that applicants were in possession of a genus of methionine repressors encoded by a genus of endogenous *metJ* genes of any nucleotide sequence and structure, a genus intracellular homoserine transsuccinylase enzymes encoded by a genus of *metA* genes, a genus S-adenosylmethionine synthetase enzymes encoded by a genus of endogenous *metK* genes, a genus of intracellular cystathionine γ -synthase enzymes encoded by a genus of *metB* genes, and a genus aspartokinase-homoserine dehydrogenase II enzymes encoded by a genus of *metL* genes for use in the claimed method.

Furthermore, the claims stand rejected for reciting gene elements, which are not described by the specification as stated in the previous Office Action dated 06/02/2005. Gene elements which are not particularly described, including regulatory elements and untranslated regions, are essential to the function of the claimed invention since the claims recite *metA*, *metK*, *metB*, and *metL* genes. The art indicates that the structure of genes with regulatory elements and untranslated regions is empirically determined. Therefore, the structure of these elements which applicants considers as being essential to the function of the claim are not conventional in the art.

There is no known or disclosed correlation between the coding region of a polynucleotide encoding each of the recited methionine repressor, homoserine transsuccinylase, S-adenosylmethionine synthetase, and cystathionine γ -synthase and the structure of the non-described regulatory elements and untranslated regions of the gene.

In view of the above considerations, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of any genes encoding any methionine repressor, homoserine transsuccinylase, S-adenosylmethionine synthetase, and cystathionine γ -synthase.

Amending the claims to recite a polynucleotide encoding the endogenous methionine repressor comprising a specific SEQ ID NO, a polynucleotide encoding the intracellular homoserine transsuccinylase comprising a specific SEQ ID NO, a polynucleotide encoding the endogenous S-adenosylmethionine synthetase comprising a specific SEQ ID NO, a polynucleotide encoding intracellular cystathionine γ -synthase comprising a specific SEQ ID NO, a polynucleotide encoding the intracellular aspartokinase-homoserine dehydrogenase II comprising a specific SEQ ID NO may overcome this rejection.

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Conclusion

6. No claim is allowed.


7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF


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